I. Remarks

Claims 1-22 are pending in the subject application and are subject to a restriction requirement.

II. Requirement for restriction under 35 U.S.C. 121

The Office has required restriction under 35 U.S.C. § 121 to one of the following allegedly independent and distinct inventions:

I. Claims 1-13, and 17-18, drawn to an isolated nucleic acid encoding a precursor GLP-1 comprising mammalian GLP-1 linked to a heterologous signal sequence, classified in class 435, subclass 6.

II. Claims 14-16, drawn to an isolated polypeptide comprising mammalian GLP-1 linked to a heterologous signal sequence, classified in class 530, subclass 350.

III. Claims 19-22, drawn to a method of promoting insulin production in an individual comprising administering an effective amount of a nucleic acid encoding a precursor GLP-1, classified in class 424, subclass 9.1.

The Office has further required restriction under 35 U.S.C. § 121 to one of the following allegedly independent and distinct inventions:

Groups 1-10: The inventions as they pertain to each of nucleic acid sequences of SEQ ID NO: 1, 3, 5, ...17, 19.

Groups 11-20: The inventions as they pertain to each of the amino acid sequences encoding SEQ ID NOs: 2, 4, 6,...18, 20, and 21.

In the event that Applicants elect Group I and II, the Office has required that one polynucleotide sequence from Groups 1-10 must be chosen to be considered fully responsive. In the event that Group III is selected, one polypeptide sequence from Groups 11-21 must be chosen to be considered fully responsive.

III. Provisional election with traverse required under 37 C.F.R. §1.143

In compliance with 37 C.F.R. §1.143, Applicant elect Group II, Claims 14-16, drawn to an isolated polypeptide comprising mammalian GLP-1 linked to a heterologous signal sequence, classified in class 530, subclass 350, with a further election of SEQ ID NO. 4 with traverse for the reasons stated below.

Applicants note that the above restriction requirement contains some inconsistencies. Groups I and III require nucleic acid sequences while Group II requires polypeptide sequences. However, the Office has required that Applicants, if electing Group I and II, select a single polynucleotide sequence from Groups 1-10. This is logical for Group I but not for Group II. In addition, the Office has required that Applicants, if electing Group III, select a single polypeptide sequence from Groups 11-21.

Applicants believe that the Office has inadvertently reversed Groups II and III. Therefore, Applicants have elected a polypeptide sequence, SEQ ID NO.: 4 with the election of Group II above. Further, Applicants note that SEQ ID NO.: 21 is not currently claimed and is thought to have been inadvertently included as a sequence for election. Clarification on these points is respectfully requested.

IV. Request for reconsideration of the Restriction Requirement under 37 C.F.R. 1.143

In light of Applicants' election of Group II, Applicants respectfully requests a reconsideration and modification of the instant restriction requirement with respect to the restriction of Groups 11-20. Applicant asserts that the search of Groups 11-20, representing 10 polypeptide sequences, does not comprise a serious burden to the Office. Additionally, the Office has failed to set forth reasons establishing why the examination of 10 polypeptide sequences constitutes an undue burden.

The Office has instituted a policy directed to improving restriction practice within TC 1600 as stated by the publication of the TC1600 Restriction Practice Action Plan (press release on October 6, 2003). This policy emphasizes the importance of the quality and consistency of restriction practice and recognizes the need for improvements in this complex technology unit.

There are two criteria for a proper requirement for restriction between patentably distinct inventions (MPEP 803). First, the inventions must be independent or distinct. Second, there must be a serious burden on the Examiner in order to merit restriction. In the absence of a serious burden, the Examiner must examine the subject application on the merits even if it includes claims to distinct inventions. Although Groups 11-20 comprise distinct inventions, the Office has failed to set forth specific reasons that establish why the search and examination of 10 polypeptide sequences constitutes a serious burden. A mere statement that the search would constitute an undue burden does not establish that it is so. Applicant asserts that this search does not comprise such a serious burden.

First, the Office is capable of readily performing sequence searches of polypeptide sequences. The sequences present in the instant claims are relatively uncomplicated. They consist of approximately 48 to 84 amino acid residues. Additionally, Applicant has provided sequence listings for the instant sequences to allow for ease of search.

Second, the Office operates a policy wherein 10 nucleotide sequences constitute a reasonable number for examination purposes (MPEP § 803.04). This allows for the examination of up to ten independent and distinct sequences in a single application without restriction. There are no distinct limits on nucleotide sequence length and complexity in this policy, suggesting that potentially long or complicated sequences (likely longer and more complex than the instant amino acid sequences) are considered reasonable to search. Therefore, it appears that the Office readily recognizes that a search of as many as 10 sequences constitutes a reasonable search and examination burden. Applicant points to the pertinent policy behind this decision in § 803.04:

> "Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided *sua sponte* to partially waive the requirements of C.F.R. 1.141 *et seq.* and permit a reasonable number of such nucleotide sequences to be claimed in a single application."

Accordingly, Applicants assert that the search of 10 polypeptide sequences is comparable to the search burden imposed by nucleic acid sequences, which has been waived by the Commissioner. Applicant respectfully requests that the current restriction requirement, under which Applicant would be required to prosecute a number of separate patent applications at considerable cost, be modified or vacated to allow all 10 peptide sequences to be searched and examined together.

If this requirement is not modified or vacated and is made final by the Examiner, Applicant further reserves the right to petition from requirement for restriction under 37 C.F.R. §1.144.

V. Conclusion:

No fee is deemed necessary in connection with the filing of this communication. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 07-1074.

Respectfully submitted,

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Date

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